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EXAMINER	
BAXTER, ZOE E	

ART UNIT	PAPER NUMBER
3735	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/648,354	SACKELLARES ET AL.	
	Examiner	Art Unit	
	Zoe E. Baxter	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-41 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-41 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 27 August 2003 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 10/21/04, 1/20/04, and 4/25/06 2B
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to because reference numbers 342, 369, 371, 375 and 393 are not defined in the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities: reference number 342 in figure 3A is not defined in the specification and reference numbers 369, 371, 375 and 393 are not defined in the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by relatively disentrainment following seizures.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 6-24, 26-32 and 34-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Iasemidis et al. (WO 01/21067). Iasemidis et al. teach a method of analyzing a multidimensional system comprising the steps of:

a. Acquiring a plurality of signals, each signal representing a corresponding channel that is associated with a different spatial location of the multi-dimensional system (page 7 lines 11-14).

b. Generating a phase space representation for each channel as a function of the corresponding one of the plurality of signals (page 7 lines 14-15).

c. Generating a signal profile for each phase space representation, each signal profile reflecting a rate of divergence of the corresponding phase space representation (page 13 lines 17-22).

d. For a selected predictor, chosen from amongst a number of possible predictors, deriving a signal profile for one or more critical channel groups, each signal profile reflecting a level of correlation between the channels of each critical channel group (page 7 lines 15-20)

e. Characterizing the state dynamics of the multidimensional system as a function of the signal profile associated with at least one critical channel group (page 7 lines 20-22).

3. Claim 2: Iasemidis et al. teach a method comprising the step of comparing each signal profile associated with a critical channel group to a threshold value, wherein said step of characterizing the state dynamics of the multidimensional system is based on the result of the comparison (page 7 lines 20-22).

4. Claim 6: Iasemidis et al. teach a method comprising the steps of:

a. Detecting a system event indicative of non-chaotic system behavior (page 14 lines 3-5).

b. For each of a plurality of predictors, deriving a signal profile for each channel groups, each signal profile reflecting a level of correlation between the channels of each channel group (page 7 lines 15-22).

c. For each of the plurality of predictors, identifying a number of critical channel groups (page 14 lines 6-7).

5. Claim 7: Iasemidis teach a method comprising the step of: choosing the selected predictor from amongst the plurality of predictors as a function of the signal profiles reflecting level of correlation for the critical channel groups associated with each predictor (page 7 lines 15-18).

6. Claim 8: Iasemidis et al. teach a method comprising the step of: after each of a number of system events, updating the number of critical channel groups of each predictor (page 14 line 21-page 15 line 5).

7. Claim 9: Iasemidis et al. teach a method comprising the step of: choosing the selected predictor from amongst the plurality of predictors as a function of the signal profiles reflecting level of correlation for the critical channel groups associated with each predictor (page 7 line 29-page 8 line 4).

8. Claim 10: Iasemidis et al. teach a method wherein said step of identifying the number of critical channel groups for each predictor is based on the signal values in a

limited portion of the level of correlation signal profile associated with each channel group of each predictor, preceding the system event (page 14 lines 8-13).

9. Claim 11: Iasemidis et al. teach a method wherein said step of identifying the number of critical channel groups for each predictor is based on the signal values in a limited portion of the level of correlation signal profile associated with each channel group of each predictor, subsequent to the system event (page 14 lines 6-7).

10. Claim 12: Iasemidis et al. teach a method of providing seizure warnings comprising the steps of:

a. Acquiring a plurality of time-series signals, each signal associated with a different location of the brain, and where each signal and its corresponding location constitute a corresponding channel (page 7 lines 25-27).

b. Generating a spatio-temporal response for each channel as a function of a corresponding one of the time-series signals (page 7 lines 15-18).

c. Generating a signal profile for each spatio-temporal response, each signal profile comprising a sequence of chaoticity values reflecting a rate of divergence of the corresponding spatio-temporal response (page 13 lines 17-22).

d. Detecting at least one seizure-related event (page 8 lines 5-8).

e. After each at least one seizure-related event, determining, for each of a plurality of predictors, a level of entrainment associated with each channel group for each predictor, and based on the level of entrainment associated

with each channel group, determining a number of critical channel groups for each predictor (page line 29-page 8 line 8).

f. Choosing a selected predictor from amongst the plurality of predictors based on the level of entrainment of the critical channel groups associated with each predictor (page 14 lines 5-9).

g. Determining when the level of entrainment associated with one or more of the critical channel groups of the selected predictor is statistically significant (page 8 lines 16-18).

h. Generating a seizure warning when it is determined that the level of entrainment associated with at least one critical channel group of the selected predictor is statistically significant (page 8 lines 4-8).

11. Claim 13: Iasemidis et al. teach a method including a step of generating a signal profile for each spatio-temporal response involves generating a sequence of Lyapunov exponent values for each spatio-temporal response (page 6 lines 19-21).

12. Claim 14: Iasemidis et al. teach a method wherein the Lyapunov exponent values are short-term Lyapunov exponent values (page 6 lines 19-20).

13. Claim 15: Iasemidis et al. teach a method wherein said step of determining, for each of the plurality of predictors, the level of entrainment associated with each channel group is based on the level of entrainment within a time window, the majority of which precedes the at least one seizure-related event, where the at least one seizure-related event is an entrainment transition event (page 19 lines 10-14).

14. Claim 16: Iasemidis et al. teach a method wherein said step of determining, for each of the plurality of predictors, the level of entrainment associated with each channel group is based on the level of entrainment within a first time window preceding the at least one seizure-related event and a second time window subsequent to the at least one seizure-related event, where the at least one seizure-related event is a seizure (page 19 lines 14-22).

15. Claim 17: Iasemidis et al. teach a method of determining, for each of the plurality of predictors, the level of entrainment associated with each channel group comprises the step of: generating a sequence of T-index values for each channel group (page 20 lines 2-13).

16. Claim 18: Iasemidis et al. teach a method including a step of choosing the selected predictor from amongst the plurality of predictors comprises the step of: comparing the level of entrainment associated with the critical channel groups of each of the plurality of the predictors (page 21 lines 12-15).

17. Claim 19: Iasemidis et al. teach a method wherein the selected predictor has critical channel groups that exhibit relatively high levels of entrainment prior to seizures as compared to the critical channel groups associated with other predictors (page 21 lines 5-15).

18. Claim 20. Iasemidis et al. teach a method wherein the selected predictor has critical channel groups that exhibit disentrained following seizures as compared to the critical channel groups associated with other predictors (page 21 line 3).

19. Claim 21: Iasemidis et al. teach a method wherein the selected predictor has critical channel groups that exhibit relatively high levels of entrainment during entrainment transition events as compared to the critical channel groups associated with other predictors (page 21 lines 5-15).

20. Claim 22: Iasemidis et al. teach a method wherein the selected predictor has critical channel groups that exhibit relatively high levels of entrainment prior seizures and entrainment transition events (page 21 lines 5-15) and relatively disentrainment following seizures (page 21 line 3).

21. Claim 23: Iasemidis et al. teach a method of determining when the level of entrainment associated with one or more of the critical channel groups of the selected predictor is statistically significant comprises the step of: comparing the level of entrainment associated with each critical channel group of the selected predictor to at least one threshold value (page 22 lines 15-18).

22. Claim 24: Iasemidis et al. teach a method of comparing the level of entrainment associated with each critical channel group of the selected predictor to at least one threshold value comprises the step of: comparing the level of entrainment associated with each critical channel group of the selected predictor to an entrainment threshold value (page 22 lines 12-18).

23. Claim 26: Iasemidis et al. teach a method comprising the step of: generating a seizure prediction when it is determined that the level of entrainment associated with at least one critical channel group of the selected predictor is statistically significant (page 8 lines 18-21).

24. Claim 27: Iasemidis et al. teach a method comprising the step of: updating each critical channel group of the selected predictor after each subsequent seizure-related event (page 14 line 19-page 15 line 6).

25. Claim 28: Iasemidis et al. teach a method wherein said step of updating each critical channel group of the selected predictor comprises the step of: reselecting one or more critical channel groups for the selected predictor as a function of the level of entrainment, associated with each channel group of the selected predictor, within a time window, the majority of which precede the seizure-related event, where the seizure-related event is an entrainment transition event (page 14 line 19-page 15 line 6).

26. Claim 29: Iasemidis et al. teach a method wherein said step of updating each critical channel group of the selected predictor comprises the step of: reselecting one or more critical channel groups for the selected predictor as a function of the level of entrainment, associated with each channel group of the selected predictor, within a first time window preceding the seizure-related event and a second time window following the seizure-related event, where the seizure-related event is a seizure (page 14 line 19-page 15 line 6).

27. Claim 30: Iasemidis et al. teach a method of providing seizure warnings comprising the steps of:

a. Choosing a selected predictor from amongst a plurality of predictors (page 21 lines 25-28).

b. Acquiring a plurality of time-series signals, each signal associated with a different location of the brain, and where each signal and its

corresponding location constitute a corresponding channel (page 7 lines 25-27).

c. Generating a spatio-temporal response for each channel as a function of a corresponding one of the time-series signals (page 7 lines 27-28)

d. Generating a signal profile for each spatio-temporal response, each signal profile comprising a sequence of chaoticity values (page 7 lines 28-30) reflecting a rate of divergence of the corresponding spatio-temporal response (page 13 lines 17-22).

e. Determining whether the level of entrainment associated with one or more critical channel groups of the selected predictor is statistically significant (page 8 lines 5-6).

f. Generating a seizure warning if it is determined that the level of entrainment associated with one or more critical channel groups of the selected predictor is statistically significant (page 8 lines 6-8).

28. Claim 31: Iasemidis et al. teaches a method including the step of determining whether the level of entrainment associated with one or more critical channel groups of the selected predictor is statistically significant comprises the step of: comparing the level of entrainment associated with each of the one or more critical channel groups of the selected predictor to at least one threshold value (page 22 lines 15-18).

29. Claim 32: Iasemidis et al. teach a method including the step of comparing the level of entrainment associated with each of the one or more critical channel groups of the selected predictor to at least one threshold value comprises the step of: comparing

the level of entrainment associated with each of the one or more critical channel groups of the selected predictor to an entrainment threshold value (page 22 lines 12-18).

30. Claim 34: Iasemidis et al. teach a method comprising the step of: generating a seizure prediction when it is determined that the level of entrainment associated with one or more critical channel groups of the selected predictor is statistically significant (page 8 lines 18-21).

31. Claim 35: Iasemidis et al teach a method further comprising the step of: updating the one or more critical channel groups of the selected predictor after each seizure-related event (page 14 line 19-page 15 line 6).

32. Claim 36: Iasemidis et al. teach a method of wherein the step of updating the one or more critical channel groups of the selected predictor comprises the step of: reselecting the one or more critical channel groups of the selected predictor as a function of the level of entrainment, associated with each channel group of the selected predictor, within a time window, the majority of which precedes the seizure-related event, where the seizure-related event is an entrainment transition event (page 14 line 19-page 15 line 6).

33. Claim 37: Iasemidis et al. teach a method wherein said step of updating the one or more critical channel groups of the selected predictor comprises the step of: reselecting the one or more critical channel groups of the selected predictor as a function of the level of entrainment, associated with each channel group of the selected predictor, within a first time window preceding the seizure-related event and a second

time window following the seizure-related event, where the seizure-related event is a seizure (page 14 line 19-page 15 line 6).

34. Claim 38: An apparatus providing seizure interdiction comprising:

a. A plurality of sensors, each configured for acquiring a time-series signal associated with a corresponding location of a patient's brain (page 8 lines 24-25)

b. Processing means for generating a seizure warning based on the time-series signals (page 8 lines 26-28).

c. Means for receiving the time-series signals wherein each time-series signal along with the corresponding location of the patient's brain constitutes a separate channel (page 13 lines 10-13).

d. Means for generating a phase space representation for each channel as a function of the corresponding one of the plurality of signals page 13 lines 17-18).

e. Means for generating a signal profile for each phase space representation, each signal profile reflecting a rate of divergence of the corresponding phase space representation (page 13 lines 19-20).

f. Means for deriving a signal profile for each of a number of critical channel groups associated with a selected predictor, chosen from amongst a number of predictors, each signal profile reflecting a level of entrainment among the channels of each critical channel group (page 13 lines 21-26).

g. Means for determining whether a level of entrainment associated with one or more critical channel groups of the selected predictor is statistically significant (page 9 lines 4-6).

h. Means for generating a seizure warning if it is determined that the level of entrainment associated with one or more critical channel groups of the selected predictor is statistically significant (page 9 lines 6-8)

i. A seizure interdiction device coupled to said processing means, said seizure interdiction device comprising means for delivering antiseizure treatment to the patient if a seizure warning signal is generated (page 9 lines 8-11).

35. Claim 39: Iasemidis teach a processing means further comprises: means for updating the one or more critical channel groups for the selected predictor after each of a number of seizure-related events. Iasemidis et al. teach that it is a very important part of the invention to be able to continuously update the list of critical channels therefore it would be inherent that the apparatus' processing means has the ability to update the critical channels (page 14 lines 21-24).

36. Claim 40: Iasemidis et al. teach a means for updating the one or more critical channel groups comprises: means for reselecting the one or more critical channel groups of the selected predictor as a function of the level of entrainment, associated with each channel group of the selected predictor, within a time window, the majority of which precedes the seizure-related event, where the seizure-related event is an entrainment transition event. Iasemidis et al. teach in figure 3 that following a seizure

event the system goes back to the initial step of declaring the critical channels as stated above (figure 3).

37. Claim 41: Iasemidis et al. teach a method wherein the means for updating one or more critical channel groups comprises: means for reselecting the one or more critical channel groups of the selected predictor as a function of the level of entrainment, associated with each channel group of the selected predictor, within a first time window preceding the seizure-related event and a second time window following the seizure-related event, where the seizure-related event is a seizure. Iasemidis et al. teach the importance of the systems ability to continuously update the list of critical channels in updating the critical channels (page 14 lines 21-24) which is shown in figure 3 the final step of the flow chart returns to the beginning in which the entire process starts over and all the steps including selecting the critical channels and evaluating the time windows are repeated.

Claim Rejections - 35 USC § 103

38. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

39. Claims 3-5, 25, 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iasemidis et al. in view of Ochs (U.S. Patent No. 5365939). Iasemidis teaches a method comprising the step of comparing each signal profile associated with a critical

channel to a T index value which indicates the measurement of entrainment (page 21 lines 6-7) and comparing the T index value to threshold value (page 22 lines 15-18) is essentially comparing an entrainment value to a threshold value. Iasemidis et al fail to teach using a disentrainment value for comparison. Ochs teaches that disenrtrainment refers to the disruption of entrained brain waves (column 2 lines 47-48). It would be obvious to one skilled in the art that a comparison of entrainment is inherently a comparison of disentrainment since the two values are opposite one another. Iasemidis determines entrainment continuously meaning it inherently determines when the subject falls out of entrainment, which would be in disentrainment.

40. Claim 4: Iasemidis et al. teach the method of determining when the critical channel drops below the entrainment threshold value using a T index value threshold (page 22 lines 10-29). Iasemidis et al. fail to teach a method of comparing the disentrainment value. As stated above Ochs teaches the disentrainment again it would be obvious to one skilled in the art to use disentrainment because it is inherently the opposite of using entrainment.

41. Claim 5: Iasemidis et al. teach that the threshold value for the T index which indicates the measurement of entrainment (page 21 lines 15-18) is adaptive since it may be adjusted to increase or decrease the sensitivity making it an adaptive parameter since it can adapt to different conditions and reduce the incidence of false alarms (page 22 lines 25-29).

42. Claim 25: Iasemidis et al. teach the method of comparing the level of entrainment associated with each critical channel group of the selected predictor to at

least one threshold value (page 22 lines 12-29). Iasemidis et al. fail to teach the step of: comparing the level of entrainment associated with each critical channel group of the selected predictor to a disentrainment threshold value, and wherein a determination that the level of entrainment associated with one or more of the critical channel groups of the selected predictor is statistically significant involves a determination that the level of entrainment has exceeded the disentrainment threshold value and subsequent thereto dropped below the entrainment threshold. As stated above Ochs teaches the disentrainment, which would be obvious to one skilled in the art to use disentrainment since it is the opposite of entrainment and it would give a further limitation on the comparison of entrainment values.

43. Claim 33: Iasemidis et al. teaches a method of comparing the level of entrainment associated with each of the one or more critical channel groups of the selected predictor to at least one threshold value (page 22 lines 12-29). Iasemidis et al fail to teach the step of: comparing the level of entrainment associated with each of the one or more critical channel groups of the selected predictor to a disentrainment threshold value, and wherein a determination that the level of entrainment associated with one or more of the critical channel groups of the selected predictor is statistically significant involves a determination that the level of entrainment has exceeded the disentrainment threshold value and subsequent thereto dropped below the entrainment threshold. As stated above Ochs teaches the disentrainment, which would be obvious to one skilled in the art to use disentrainment since it is the opposite of entrainment and it would give a further limitation on the comparison of entrainment values.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zoe E. Baxter whose telephone number is 571-272-8964. The examiner can normally be reached on Monday-Friday 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zoe E. Baxter
Examiner
Art Unit 3735

ZEB

ROBERT L. NASSER
PRIMARY EXAMINER